



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0748]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups About Drug Products as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0677. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Focus Groups About Drug Products as Used by the Food and Drug Administration--(OMB Control Number 0910-0677)--Extension

Focus groups provide an important role in gathering information because they allow for a more in-depth understanding of individuals' attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative research tool have three major purposes:

- To obtain information that is useful for developing variables and measures for quantitative studies,
- To better understand people's attitudes and emotions in response to topics and concepts, and
- To further explore findings obtained from quantitative studies.

FDA will use focus group findings to test and refine its ideas and to help develop messages and other communications, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

FDA's Center for Drug Evaluation and Research, Office of the Commissioner, and any other Centers or Offices conducting focus groups about regulated drug products may need to conduct focus groups on a variety of subjects related to consumer, patient, or healthcare professional perceptions and use of drug products and related materials, including but not limited to:

- direct-to-consumer prescription drug promotion,
- physician labeling of prescription drugs,
- Medication Guides,
- over-the-counter drug labeling,
- emerging risk communications,
- patient labeling,
- online sales of medical products, and
- consumer and professional education.

Annually, FDA projects about 20 focus group studies using 160 focus groups with an average of 9 persons per group, and lasting an average of 1.75 hours each. FDA is requesting this burden for unplanned focus groups so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

In the Federal Register of June 28, 2013 (78 FR 38993), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this information collection as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Focus Groups About Drug Products	1,440	1	1,440	1.75	2,520

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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